REMARKS/ARGUMENTS

Claim 1 is amended. Claims 2-23 remain unchanged.

Reconsideration of the claims rejection is requested and allowance of all claims is solicited in view of the above-mentioned amendments and the arguments below.

35 USC §103 Rejection

Independent claims 1 and 23 were rejected under 35 USC §103(a) as being unpatentable over Sherman et al (US6419958) in view of Oosterbaan et al (US 6696496) and further in view of Mulye (US 2002/0155156). Claims 2-22 depend upon claim 1 and were also rejected under 35 USC §103(a) as being unpatentable over Sherman et al (US6419958) in view of Oosterbaan et al (US 6696496) and further in view of Mulye (US 2002/0155156).

The rejection of claims 1-23 is respectfully traversed for the following reasons.

Neither Sherman et al, nor Oosterbaan et al, nor Mulye alone or in combination teach or suggest developing a once a day extended release formulation of Venlafaxine HCL, that comprises a hard gelatin capsule containing a therapeutically effective number of mini tablets, where each mini tablet comprises a functional core and a functional coating and where the functional coating limits the initial rapid diffusion of the Venlafaxine HCL drug contained in the functional core.

It was acknowledged in the office action of 9/30/09 that "Sherman does not teach the controlled release formulation of Venlafaxine HCl in the form of mini-tablets and the functional coating of claims 6-17" (page 4, lines 14-16 of the office action of 9/30/09). In other words, Sherman does not teach a Venlafaxine HCL mini-tablet with a functional coating where the functional coating limits the initial rapid diffusion of the Venlafaxine HCL drug contained in the mini-tablet.

It was also acknowledged in the office action of 9/30/09 that "Oosterbaan is not referring to 24-hour extended release Venlafaxine mini-tablets" (page 14, lines 11-12of the office action). Actually, the subject-matter of Oosterbaan et al (US 6696496) is limited only to Venlafaxine salts which have lower water-solubility relative to Venlafaxine HCL. Furthermore, Oosterbaan et al does not teach coating the Venlafaxine salt tablets with a functional coating that limits the initial rapid diffusion of the Venlafaxine HCL drug contained in the functional core.

Mulye (US 2002/0155156) teaches coating a solid dosage form of a medicament in order to produce controlled release of the active ingredient. However, nowhere, in the entire application Venlafaxine HCL is disclosed as being an active agent the release of which can be controlled by the disclosed coating. Furthermore, there is no suggestion to use the disclosed coating in order to limit the initial rapid diffusion of the Venlafaxine HCL drug contained in the functional core of a mini-tablet.

Based on the above mentioned reasons it is concluded that neither Sherman et al nor Oosterbaan et al nor Mulye alone or their combination teach or suggest developing a once a day extended release formulation of Venlafaxine HCL, that comprises a hard gelatin capsule containing a therapeutically effective number of mini tablets, where each mini tablet comprises a functional core and a functional coating and where the functional coating limits the initial rapid diffusion of the Venlafaxine HCL drug contained in the functional core. Accordingly, it is concluded that claim 1 is patentable over Sherman et al, Oosterbaan et al, Mulye alone or in combination.

Claims 2-22 depend directly or indirectly upon claim 1 and since claim 1 is patentable over Sherman et al, Oosterbaan et al, Mulye alone or in combination, they should also be patentable over Sherman et al, Oosterbaan et al, Mulye alone or in combination.

Claim 23 is a method claim corresponding to compound claim 1 and since claim 1 is patentable over Sherman et al, Oosterbaan et al, Mulye alone or in combination, claim 23

should also be patentable over Sherman et al, Oosterbaan et al, Mulye alone or in combination.

It is believed that all of the pending claims have been addressed in this paper. Failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. Nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

In view of the above, it is submitted that claims 1-23 are in condition for allowance. Reconsideration of the claims rejection is requested and allowance of all claims at an early date is solicited.

If this response is found to be incomplete, or if a telephone conference would otherwise be helpful, please call the undersigned at 781-235-4407

Respectfully submitted,

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I hereby certify under 37 CFR 1.10 that this correspondence is being electronically at the USPTO on the date indicated above and is addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450